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September 8, 2009

## **BY ECF**

Honorable Katharine S. Hayden, U.S.D.J. United States District Court District of New Jersey Martin Luther King, Jr. Federal Building and Courthouse 50 Walnut Street Newark, New Jersey 07102

Re: PDL BioPharma, Inc., et al. v. Sun Pharmaceutical Industries Ltd.

Civil Action No. 07 CV 1788 (KSH) (PS)

Dear Judge Hayden:

As Your Honor is aware, this firm represents Defendant Sun Pharmaceutical Industries LTD. in the above-captioned matter. Enclosed please find a copy of correspondence we submitted earlier today to Your Honor by hand delivery. Our messenger picked up the papers from our office at approximately 2:40 pm, but it is our understanding from speaking with Your Honor's deputy clerk that this letter, along with the attachments, did not make it to Your Honor's chambers. We apologize for this and we have now filed the opposition brief by ECF.

Additionally, although we indicated in the attached correspondence that we would be filing a motion to seal, upon further review of the brief, we do not believe the brief contains any confidential materials and, thus, we do not intend to file a motion to seal.

Honorable Katharine Hayden, U.S.D.J. September 8, 2009 Page 2

We are available to discuss these issues with Your Honor at Your Honor's convenience.

Respectfully submitted,

Yames S. Richter

cc: All Counsel of Record (w/encl.)(by e-mail)

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September 8, 2009

## **BY HAND DELIVERY**

Honorable Katharine S. Hayden, U.S.D.J. United States District Court District of New Jersey Martin Luther King, Jr. Federal Building and Courthouse 50 Walnut Street Newark, New Jersey 07102

Re: PDL BioPharma, Inc., et al. v. Sun Pharmaceutical Industries Ltd.

Civil Action No. 07 CV 1788 (KSH) (PS)

# Dear Judge Hayden:

As Your Honor is aware, this firm represents Defendant Sun Pharmaceutical Industries LTD. in the above-captioned matter. Pursuant to our telephone conference with Your Honor this morning, enclosed please find two courtesy copies of the following:

1. Sun's Brief in Opposition to EKR's Application for a Temporary Restraining Order.

We are in the process of preparing and filing by ECF a motion to seal and a redacted and confidential version of the Brief.

Additionally, in response to Your Honor's inquiry regarding whether Sun will agree to provide notice to EKR once it receives approval from the FDA, we sent an email to our client immediately after our conference call with Your Honor. Because Sun is located in Mumbai, India, the local time there was approximately 9:00 pm. We could not reach our client due to this time difference, but we will agree to provide immediate notice to Your Honor and EKR, as we assume Sun's intent is to launch once final approval is received from the FDA.

Honorable Katharine Hayden, U.S.D.J. September 8, 2009 Page 2

Finally, during this morning's telephone conference, Your Honor expressed surprise that this issue was being raised at this stage of the litigation, and seemed to suggest that Sun somehow previously misrepresented the landscape of this litigation in prior communications to Your Honor. In fact, EKR latched onto this and called it a game of "cat and mouse." We respectfully submit that the issues raised in the current application have been known to the parties, and have been part of the record, since the Complaint was filed in 2007.

Sun first asserted invalidity as a defense in its initial answer to the complaint, and subsequently added a counterclaim for invalidity in response to EKR's second amended complaint. Thus, Sun has always maintained that the '405 patent-in-suit is invalid. Sun simply chose to move for summary judgment on its noninfringement defense, rather than invalidity, because Magistrate Judge Shwartz indicated early on that it was less likely Sun would be permitted to file an early summary judgment motion directed towards invalidity. However, both parties were well aware that Sun's invalidity defense would have to be litigated before final judgment could be entered in this matter.

In fact, at the last hearing before Your Honor on July 27, 2009 (in which the parties presented oral argument in connection with EKR's *Daubert* motions), EKR's counsel expressly raised this issue and advised Your Honor of the potential that EKR would be applying for a TRO on or around September 5, which is when the 30-month stay of FDA approval of Sun's pending application expired. EKR did not file until this morning because, at EKR's request, Sun agreed not to launch its product until at least Wednesday, September 9<sup>th</sup>.

Contrary to EKR's comments this morning, Sun has not been "playing games" here, but rather has been unduly cooperative on this front. This does not change the fact, however, that Sun has always maintained that the '405 patent is invalid and is eager to set forth its invalidity defense which, as set forth in its opposition brief, has substantial merit.

Respectfully submitted,

ASRetitos James S. Richter

cc: All Counsel of Record (w/encl.)(by e-mail)